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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,715	01/09/2002	Jeanette McCarthy	VTY2002-01R	6424

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,715

Applicant(s)

MCCARTHY, JEANETTE

Examiner

Marjorie A. Moran

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 50-57 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 15-21 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8-14, 22-24, 28-30 and 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election of Group I, claims 1-30 and 50-57, and of species (C) vascular imaging in the reply filed on 4/15/04, and of the species of angiography in the reply filed 9/16/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-7, 15-21, and 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 4/15/04 and 9/16/04.

Claims 1-30 and 50-57 are pending. An action on the merits of elected claims 1-2, 8-14, 22-24, 28-30 and 50-57, as they read on the elected species, follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 8-9, 50-52, and 54-56 are rejected under 35 U.S.C. 102(a) as being anticipated by MATSUO et al. (Circulation (10/23/2001) volume 104, no. 17 Supp. p. II.611).

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MATSUO teaches a method of identifying/diagnosing subjects for further evaluation, who are at risk of myocardial infarction, by identifying a Lys198Asn polymorphism in the endothelin-1 gene (abstract). It is noted that position 198 in MATSUO's gene corresponds to a change in G to T at position 159858 in instant SEQ ID NO: 1 and at position 159908 of gi:2791272 (Genbank ID), thus claims 8-9, 50-52 and 54-56 are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 10-14, 22-24, 28-30, 53, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over MATSUO et al. (Circulation (10/23/2001) volume 104, no. 17 Supp. p. II.611) as applied to claims 8-9, 50-52, and 54-56 above, and further in view of JADVAR et al. (US 5,010,888).

MATSUO teaches a method of identifying/diagnosing subjects who are at risk for myocardial infarction by identifying a polymorphism in the EDN-1 gene, as set forth above. MATSUO does not teach identifying a subject for a clinical course of therapy or benefit of further diagnostic evaluation, specifically angiography. MATSUO does not teach evaluating risk/diagnosis of coronary artery disease.

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JADVAR teaches that coronary artery disease and myocardial infarction are linked, and teaches that a variety of techniques, including angiography, may be used to detect either or both of myocardial infarction and coronary artery disease (col. 1, lines 40-58). JADVAR also teaches that early detection of coronary artery disease is desired to reduced the effects of myocardial infarction (col. 1, lines 49-50).

It would have been obvious to one of skill in the art at the time of invention to have identified a subject for angiography and identification of possible coronary artery disease, as taught by JADVAR, using the diagnostic method of MATSUO, where the motivation would have been to diagnose possible coronary artery disease and/or potential of infarction as early as possible, as taught by JADVAR. Identification of possible coronary artery disease and myocardial infarction in combination with angiography would have been considered an improvement in the art as JADVAR teaches that methods such as angiography are expensive or invasive, thus identification of the polymorphism of MATSUO would identify those likely to be at risk, while the angiography of JADVAR would confirm, or dispel, the risk identification.

Conclusion

Claims 1-2, 8-14, 22-24, 28-30 and 50-57 are rejected; claims 3-7, 15-21, and 25-27 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

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272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
12/13/04